

## A newly designed fully covered metal stent for lumen apposition in EUS-guided drainage and access: a feasibility study (with videos)

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**Background:** A lumen-apposing stent can be used effectively under endosonographic guidance.

**Objective:** To evaluate a newly designed, fully covered self-expandable metal stent with folding anchoring flanges for lumen apposition assembled on a conventional delivery system.

**Design:** Retrospective case series and animal study.

**Setting:** Tertiary care academic medical centers.

**Subjects:** Six pigs for animal study and 7 patients, 3 of whom underwent endoscopic drainage for acute cholecystitis (AC) and 4 for pancreatic fluid collection (PFC).

**Intervention:** Stent deployment under EUS guidance after puncturing, passage of an endoscope through the stent into the gallbladder (GB), or PFC with conventional endoscopic procedures.

**Main Outcome Measurements:** Technical and clinical success, adverse events, and removability.

**Results:** In the animal study, the stent was successfully inserted and deployed in the GB via a transgastric approach under EUS guidance without adverse events in all 6 pigs. Contrast injection demonstrated the absence of leakage. Cholecystoscopy with enhanced endoscopy was performed successfully in all animals after stent placement. All stents were intact and were removed successfully at 4 weeks. GB firmly adhered to the stomach with an intact cholecystogastric tract on necropsy and histopathology. The stents were successfully deployed without adverse effects in 7 patients. AC or PFC was resolved after stent placement in all patients. Endoscopic procedures were possible through the stent. Stent migration was not observed. The stent was successfully removed from the 4 patients with PFC after complete resolution.

**Limitations:** Small sample size, retrospective study.

**Conclusions:** Transenteric drainage and endoscopic intervention by using a novel fully covered self-expandable metal stent for lumen apposition under EUS guidance is feasible for the management of AC and PFC. Further study is warranted.

*Abbreviations:* AC, acute cholecystitis; FCSEMS, fully covered self-expandable metal stent; GB, gallbladder; PFC, pancreatic fluid collection.

*DISCLOSURE:* Dr Moon is the inventor of the Niti-S Spaxus. All other authors disclosed no financial relationships relevant to this publication. This work was supported in part by the SoonChunHyang University Research Fund (Jong Ho Moon and Hyun Jong Choi).



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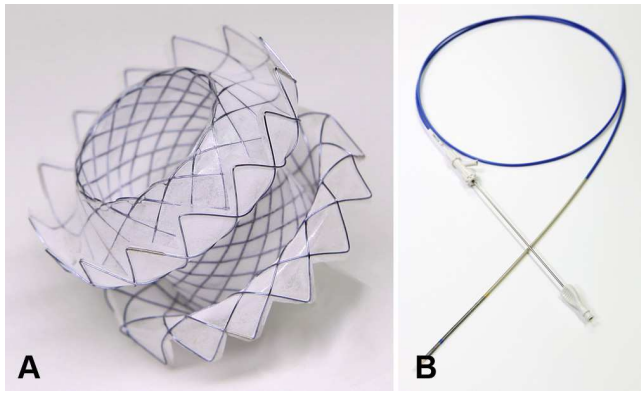
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**Figure 1.** **A,** A new fully covered metal stent having folding-back wide anchoring flanges for lumen apposition. **B,** A 10F conventional delivery system with a constrained stent.

EUS-guided transenteric drainage of pancreatic fluid collection (PFC) or of the biliary tree, including the gallbladder (GB), by using plastic or fully covered self-expandable metal stents (FCSEMSs) is now a well-established procedure.<sup>1-3</sup> However, conventional stents still have a chance of migration or leakage that can lead to serious adverse events. An FCSEMS designed as a lumen-apposing stent (AXIOS; Xlumena Inc, Mountain View, Calif) has been reported.<sup>4,5</sup> A new FCSEMS for lumen apposition with a conventional stent delivery system was developed, and we report the results of an animal study and clinical application.

## METHODS

### Newly designed FCSEMS for lumen apposition

The FCSEMS for lumen apposition (Niti-S Spaxus; Taewoong Medical Co, Ltd, Ilsan, South Korea) is made of nitinol wire and fully covered with a silicone membrane. The diameter of the flange at both ends was 25 mm to anchoring. After deployment, the anchoring flanges can be folded back to hold the 2 luminal interfaces in apposition. The available diameter of the stent is 8, 10, and 16 mm and the length is 20 mm, but the distance between the flanges is 5 mm after folding back with deployment (Fig. 1A). The margin of the flange is designed to transmit even pressure on the luminal wall, minimizing trauma. Mechanical force on both sides for apposition is applied continuously by shortening of the stent because of the unique design of the wire mesh to make an intact fistulous tract after fusion between 2 lumens and to prevent leakage outside the lumens. This stent is delivered with a 10F conventional delivery system (Fig. 1B; Video 1, available online at [www.giejournal.org](http://www.giejournal.org)), so the stent can be inserted via the working channel of an echoendoscope and deployed. There is a blue marker on the outer sheath to confirm the complete deployment of the distal flange.

### Take-home Message

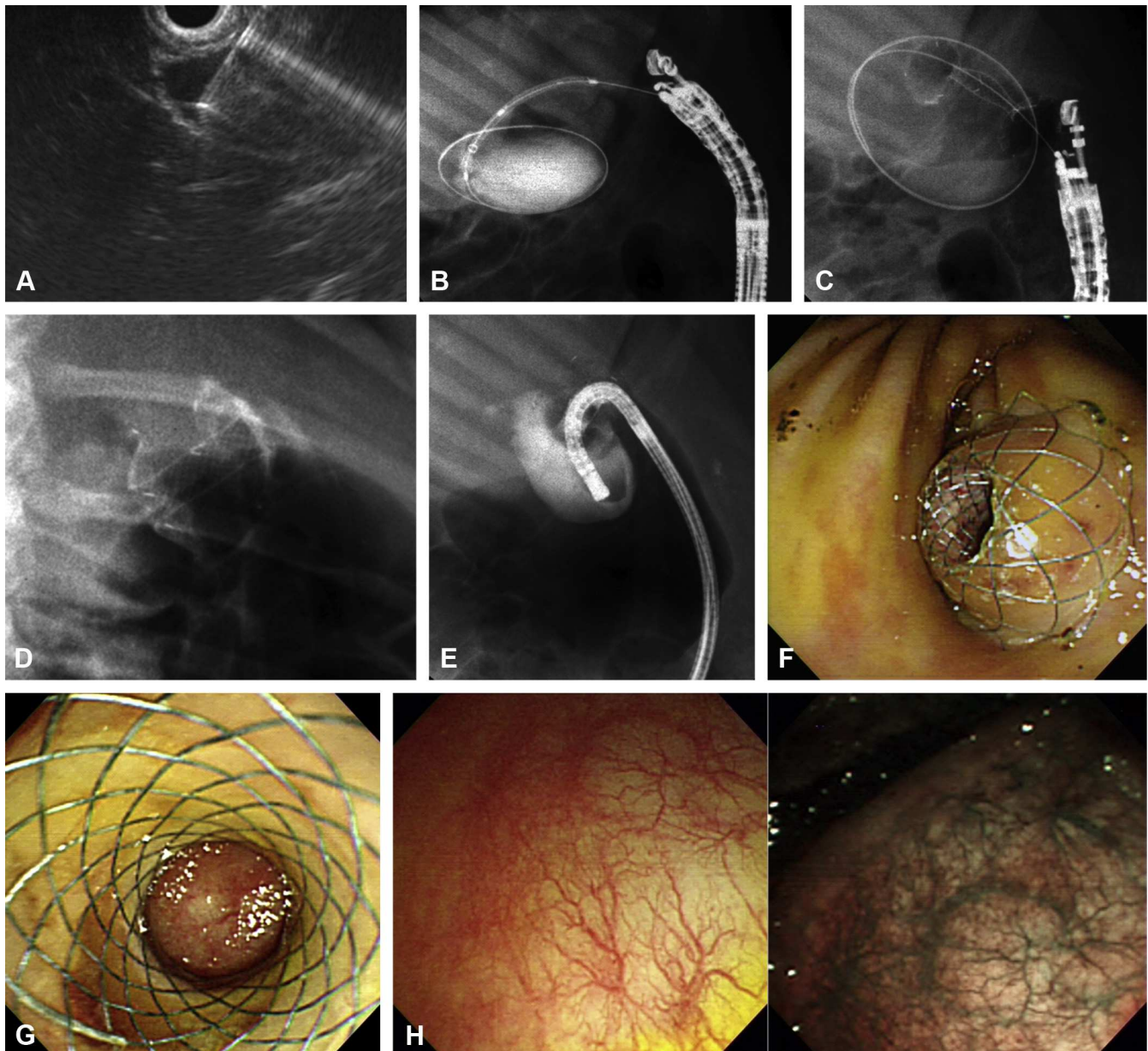
- A new, fully covered self-expandable metal stent for lumen apposition, delivered by using a conventional delivery system, was feasible for EUS-guided gallbladder and pancreatic pseudocyst drainage.
- Interventional endoscopy through this removable stent was possible without adverse events.

### Techniques

A conventional linear echoendoscope (GF-UCT140; Olympus Medical, Tokyo, Japan) was used. EUS-guided transenteric puncture was performed by using a 19-gauge needle (EchoTip Access Needle; Cook Medical, Winston-Salem, NC) with color Doppler followed by placement of a 0.035-inch guidewire. The needle was removed, and the tract was dilated over the wire by using a bougie dilator (6F-8F Soehendra dilator; Cook Medical), or a needle-type sphincterotome (Fusion Needle Knife; Cook Medical). After the initial tract dilation, a balloon catheter (4-mm Hurricane; Boston Scientific, Natick, Mass) was applied to provide sufficient dilation. The stent delivery system was inserted over the guidewire and advanced into the GB or pancreatic pseudocyst. The distal flange was deployed under EUS and fluoroscopic guidance. After complete deployment of the distal flange, proximal retraction of the delivery system was performed until the blue mark on the handle of the introducer was seen. Then, the proximal flange was slowly deployed under endoscopic guidance. After complete deployment, the deployed stent lumen was dilated up to 8 to 10 mm with a balloon catheter (Hurricane; Boston Scientific) to make complete folding back of both flanges for apposition, if needed. An ultraslim or standard diagnostic upper endoscope (Olympus Medical) was passed directly through the stent and into the GB or pancreatic pseudocyst. Subjects fasted until the next morning after the procedure. The stents were removed by using standard forceps under endoscopic guidance, if needed.

### Animal study

Six female mini pigs (*Sus scrofa*) weighing 25 to 35 kg were used for the animal study. One week before the study, the orifice of the ampulla of Vater for the bile duct was ligated with endoscopic clipping to provoke an enlarged GB. A cholecystogastrostomy tract was created under EUS guidance, and the stent was deployed across the lumen under EUS, fluoroscopic, and endoscopic guidance (Fig. 2; Video 2, available online at [www.giejournal.org](http://www.giejournal.org)). Contrast was injected in the GB through the stent to confirm the absence of leakage. Cholecystoscopy was performed immediately. The stent was removed at 4 weeks, and cholecystoscopy was performed again after stent removal. Institutional review board approval was obtained from the local animal ethics committee.



**Figure 2.** Animal study showing transgastric EUS-guided gallbladder (GB) drainage by using the new stent for lumen apposition. **A**, EUS image of puncturing the GB with a 19-gauge needle. **B, C**, Deploying the stent through the cholecystogastrostomy tract. **D**, Radiograph showing fully deployed stent. **E**, Contrast injection showing the GB without leakage. **F**, Endoscopic view of the stent on the stomach. **G**, Endoscopic view showing the GB through the entry of the stent. **H**, Endoscopic view showing the inside of the GB lumen (white-light and narrow-band imaging).

### Patients

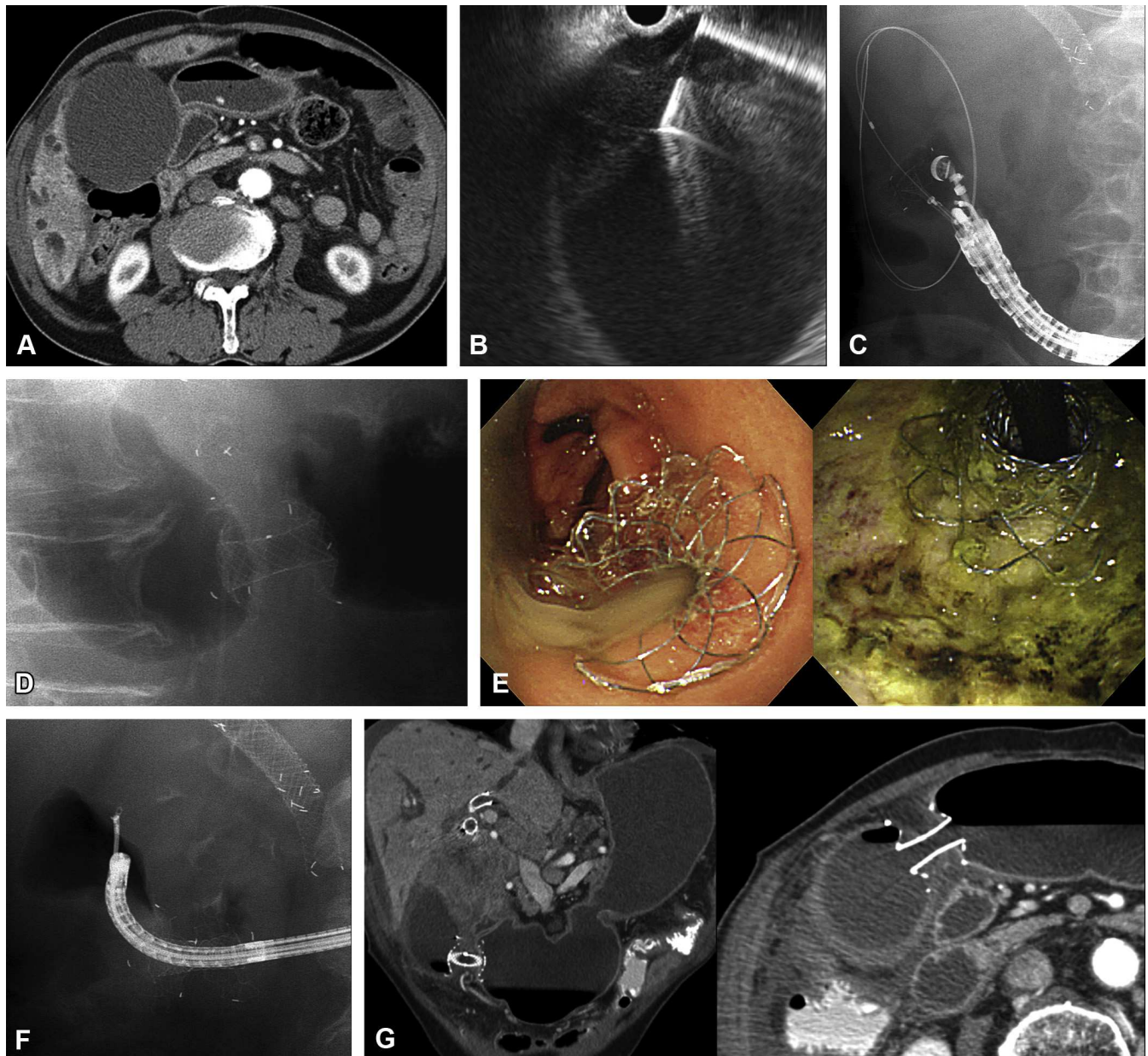
Seven patients (5 men, 2 women) underwent EUS-guided stent placement for lumen apposition for acute cholecystitis (AC) of the bile duct or GB cancer in 3 patients (Fig. 3; Video 3, available online at [www.giejournal.org](http://www.giejournal.org)) and symptomatic PFC in 4 patients (CT severity index; E in all, causes of pancreatitis; alcohol 3, gallstone 1) including 1 walled-off necrosis (Fig. 4; Video 4, available online at [www.giejournal.org](http://www.giejournal.org)) from January to May 2013. In patients with PFC, the stent was removed endoscopically after complete disappearance of the PFC,

confirmed by a CT scan (Video 5, available online at [www.giejournal.org](http://www.giejournal.org)).

Written informed consent was obtained from all enrolled patients. Institutional review board approval was obtained after completion of animal studies.

### RESULTS

The stent was deployed successfully in the GB lumen through the gastric wall in all 6 pigs. The stomach and

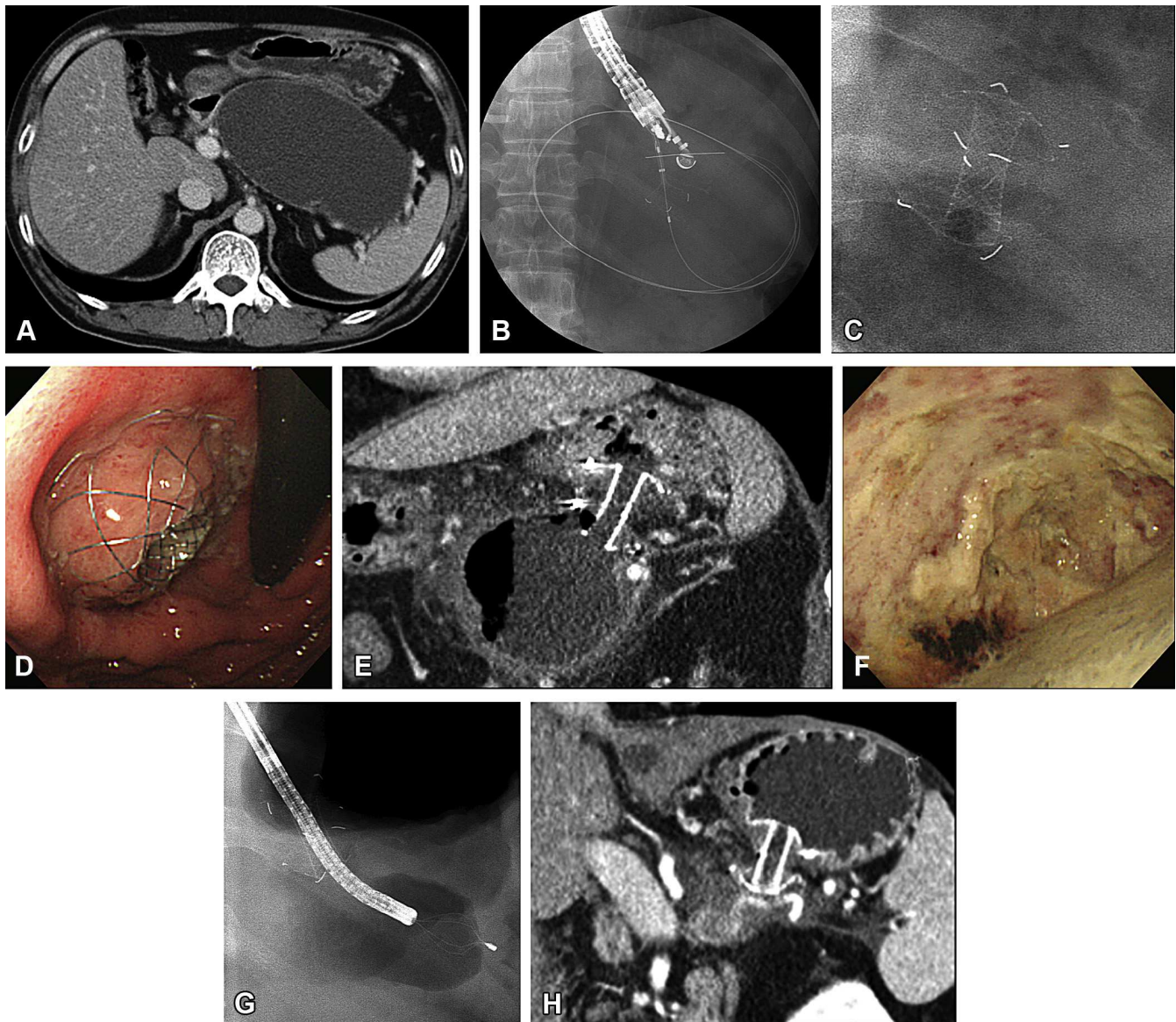


**Figure 3.** Transgastric EUS-guided gallbladder (GB) drainage by using the new stent for lumen apposition. **A**, CT showing the GB distended by bile duct cancer. **B**, EUS showing puncturing by using a 19-gauge needle. **C**, Radiograph showing deployment of the stent. **D**, Fully deployed stent. **E**, Endoscopic view of the deployed stent on the stomach and GB. **F**, Radiograph showing forceps biopsy of the GB lumen through the stent. **G**, CT showing lumen apposition between the stomach and GB by using the new stent.

GB lumen were completely connected. No adverse event was observed during the procedure. The gastroscope could be readily advanced through the stent into the GB. Contrast injection in the GB lumen showed no leakage. Stents were easily removed by using forceps at 4 weeks after stenting. The gastroscope could be inserted through the tract created to enter the lumen of the GB, even after removal of the stent. Gross pathology after necropsy showed adherence of the GB to the stomach wall around the site of cholecystogastrostomy, with a patent tract in all animals (Fig. 5A). A histopathological examination

showed complete fusion of the GB and gastric wall, with mature fibrous tissue and covering epithelium (Fig. 5B).

Stents were successfully deployed and fully expanded in all 7 patients. No early adverse event occurred in association with the procedure. Symptomatic improvement of AC and PFC was observed after stent placement in all patients with a hospital stay of 2 to 10 days (mean 4.6 days). Insertion of the gastroscope, endoscopic visualization, tissue biopsy, and necrosectomy were achieved in all patients in whom they were attempted. Stent migration was not observed in any patient. Removal of the stent was



**Figure 4.** Transgastric EUS-guided pancreatic pseudocyst (PPC) drainage by using the new stent for lumen apposition. **A**, CT showing PPC. **B**, Deploying the stent on a PPC. **C-E**, Fully deployed stent (**C**, radiograph; **D**, endoscopy; **E**, CT). **F**, Endoscopic view showing the inside of the PPC through the stent. **G**, Radiograph showing removal of necrotic tissue by using a basket. **H**, CT showing complete resolution of the PPC by drainage with the stent.

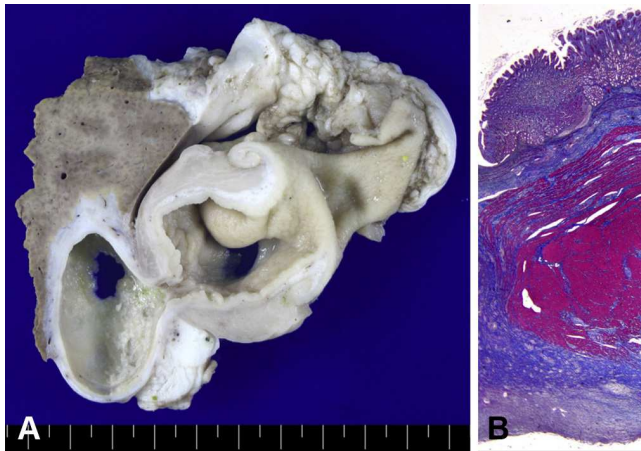
achieved with no difficulty in 4 patients with PFC, after a median time of 26 days (range 14-48 days), after confirmation of complete resolution on a CT scan. In 3 patients with the bile duct or GB cancer, AC resolved, and the stent remained in place during a median follow-up period of 5 months (range, 3-6 months).

## DISCUSSION

Plastic stent insertion for the treatment of PFC is an effective, but technically difficult procedure, even with EUS guidance.<sup>6</sup> The use of conventional FCSEMSs can be a better alternative for the treatment of PFC and AC, but

significant adverse event rates related to migration and bleeding have been reported.<sup>1</sup> EUS-guided transenteric GB drainage by using modified FCSEMSs for AC has been also reported.<sup>3</sup> However, GB drainage carries a risk of peritonitis by migration of the stent and leakage.<sup>2</sup>

Yamatomo et al<sup>7</sup> used a modified FCSEMS (Nagi stent; Taewoong Medical Co) with a lumen diameter of 16 mm and flared-end diameter of 26 mm in 9 patients with PFC. This type of FCSEMS can minimize the risk of migration, but has no lumen-apposing function. Recently, a specialized FCSEMS, designed as a lumen-apposing stent was developed (AXIOS; Xlumena) with a unique delivery system.<sup>5,8,9</sup> It has been reported that enterocystostomy by using the AXIOS stent showed a high success rate and



**Figure 5.** **A**, Gross findings showing the connecting fistulous tract between the gallbladder and stomach at the site of the cholecystogastrostomy. **B**, Histopathological findings showing fusion of gastric wall and gallbladder wall by mature fibrous tissue with re-epithelialization (trichrome stain, orig. mag.  $\times 10$ ).

was a safe alternative technique compared with conventional self-expandable metal stents.

The new FCSEMS has wide anchoring flanges that can be folded back after deployment to prevent migration and to maintain apposition. An animal study demonstrated that the new stent deployed easily on EUS and endoscopic guidance. Deployment of the distal anchoring flange was well visualized on EUS and fluoroscopy. The proximal anchoring flange was then separately deployed under endoscopic guidance. From the results of the animal study, placement of the new stent through a cholecystogastrostomy tract with EUS resulted in the complete fusion of the walls, like a single organ, with no leakage. The stent was removed easily with standard forceps. Hyperplastic tissue reaction by the new stent was not found or was minimal on endoscopic and histopathological examination during the 4-week stenting period in the animal study. We evaluated a new FCSEMS for the treatment of patients with AC and PFC after the animal study. The new stent was inserted and fully and successfully deployed to create a communicating tract in all cases. The new FCSEMS has some advantages. The most important is a simple, thin, 10F delivery system. The delivery system is almost identical to that used for conventional tubular SEMS and is familiar to the operator and assistants. The 2-cm length of the new stent facilitates easy and safe deployment. Recent reports described a spectrum of successful transenteric endoscopic interventions after placement of a self-expandable metal stent.<sup>3,10</sup>

This study had several limitations. This was a retrospective pilot study involving a small case series. The follow-up duration was short, so recurrence and other adverse events might have been underestimated.

In conclusion, EUS-guided transenteric drainage of PFC and GB using a new FCSEMS is a technically feasible endoscopic approach and provides a route for interventional endoscopic procedures. Further studies are needed to evaluate the long-term results and effectiveness compared with other stents.

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